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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,484	03/12/2001	Maria Grant	UF-10287R	1233
29847	7590	01/27/2004	EXAMINER	
BEUSSE BROWNLEE WOLTER MORA & MAIRE 390 N. ORANGE AVENUE SUITE 2500 ORLANDO, FL 32801			RUSSEL, JEFFREY E	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/804,484

Applicant(s)

GRANT, MARIA

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-15, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-15, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 1, 2003 has been entered.
2. Instant claims 3-15, 17, and 18 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/188,483 because the '483 provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the instant claimed invention. Accordingly, the Grant et al abstract (Diabetes, Vol. 48, Suppl. 1, pages A155-A156) is available as prior art against the instant claims only under 35 U.S.C. 102(a).
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 3-6, 17, and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by the Grant et al abstract (Diabetes, Vol. 48, Suppl. 1, pages A155-A156). The Grant et al abstract teaches treating diabetic retinopathy by administering a combination of octreotide and 100-200 µg/day thyroid hormone/levothyroxine.
5. Claims 7-13 are rejected under 35 U.S.C. 103(a) as being obvious over the Grant et al abstract (Diabetes, Vol. 48, Suppl. 1, pages A155-A156). Application of the Grant et al abstract

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is the same as in the above rejection of claims 3-6, 17, and 18. The Grant et al abstract does not teach it active agents in kit form in syringes or oral dosage forms, and does not teach optimizing the relative dosages of the active agents. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the active agents of the Grant et al abstract in kit form because it is routine in the pharmaceutical arts to provide active agents in kit form for ease of storage, transportation, measurement, and administration. It would further have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the active agents of the Grant et al abstract in the form of syringes or in oral dosage forms because these are conventional forms for administering pharmaceutical agents. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal dosages and relative dosages for the active agents of the Grant et al abstract because dosage is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

6. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over the Grant et al abstract (Diabetes, Vol. 48, Suppl. 1, pages A155-A156) as applied against claims 3-6, 17, and 18 above, and further in view of the Patel et al article (Endocrinology, Vol. 135, pages 2814-2817). The Grant et al abstract teaches using octreotide, but do not teach first characterizing the binding activity of the octreotide to the sstr2 receptor before their use. The Patel et al article teaches that it is known to characterize the binding activity of various somatostatin analogs, including octreotide, to various somatostatin receptors, including SSTR2 (see, e.g., Table 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to further characterize the binding activity of the octreotide of the Grant et al abstract to the

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sstr2 receptor, because the Patel et al article shows that this is a property of interest for the clinical use of somatostatin analogs, because it is routine in the pharmaceutical arts to characterize the chemical and physiological properties of therapeutic agents, and because the results of such an assay would not affect the teaching of the Grant et al abstract that octreotide is actually useful in the treatment or prevention of diabetic retinopathy.

7. Applicant's arguments filed December 1, 2003 have been fully considered but they are not persuasive.

The rejections based upon the Grant et al abstract (Diabetes, Vol. 48, Suppl. 1, pages A155-A156) as the primary reference are maintained. The declaration by Grant filed September 25, 2003 is not deemed sufficient to antedate the Grant et al abstract for the reasons set forth in the Advisory action mailed October 14, 2003. The declaration does not meet the requirements of a declaration under 37 CFR 1.131. It is the declaration itself which must allege where and when conception and/or reduction to practice occurred, and which must provide facts or documentary evidence to support these allegations. Attorney's arguments or inferences made from the cited prior art may not be relied upon to supply deficiencies in the declaration. See also the citations made in the Advisory action to the MPEP for requirements for a declaration under 37 CFR 1.131.

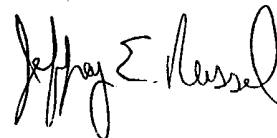
The Advisory action does not raise issues as to whether Dr. Grant conceived of the invention solely. Because of the significant deficiencies of the declaration under 37 CFR 1.131, the examiner discussed whether the declaration would satisfy the procedurally less-burdensome requirements of a Katz-type declaration under 37 CFR 1.132. If Applicant wishes to antedate the

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Grant et al abstract using the more exacting requirements of 37 CFR 1.131, she is of course entitled to do so.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (571) 272-0961. The fax number for Technology Center 1600 for formal communications is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

January 13, 2004